UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

Kathryn Ottinger,

Plaintiff,

v. Civil Action No. 2:12-CV-2

Kathleen Sebelius, Secretary of the United States Department of Health and Human Services,

Defendant.

**OPINION AND ORDER**
(Docs. 6, 7)

Plaintiff Kathryn Ottinger, appearing *pro se*, brings this action against Defendant Kathleen Sebelius, Secretary of the United States Department of Health and Human Services ("Secretary"), seeking review of the Secretary's determination that she is not entitled to coverage under Medicare Part B for the cost of intravenous (IV) daptomycin,[1] an external infusion pump, and infusion supplies, all of which were provided to her in her home from September 11, 2009 through September 25, 2009. Pending before the Court are Ottinger's motion seeking an order reversing the Secretary's decision (Doc. 6), and the Secretary's motion for judgment on the pleadings seeking dismissal of Ottinger's Complaint (Doc. 7). On November 20, 2012, the Court held a hearing on the motions. Both parties attended the hearing and presented oral argument.

[1] Daptomycin is an antibiotic "used for the treatment of complicated skin and skin structure infections." *Daptomycin Definition*, AHFS DRUG INFORMATION (2008), *available at* Lexis GENMED/DIF.

For the foregoing reasons, the Court GRANTS the Secretary's motion, and DENIES Ottinger's motion.

## Background

### I. Factual Background

Since 2009, Ottinger has treated with the Fletcher Allen Health Care Infectious Disease Clinic. (AR 153.) In May 2009, when she was approximately seventy-four years old, she had spinal fusion surgery. (AR 85, 153.) Thereafter, she developed complications, including a gallbladder rupture and a serious surgical wound infection, requiring several trips back to the operating room and multiple courses of IV antibiotics. (*Id.*) From August until the beginning of September 2009, Ottinger underwent acute rehabilitation at the Burlington Health and Rehabilitation Center for her surgical infection. (AR 85, 152.) After developing an allergic reaction to the antibiotic vancomycin, she was switched to daptomycin. (AR 152.) In a letter from March 2010, Dr. Susan Shull, Ottinger's physician at the Rehabilitation Center, explained that, "[r]ehab was indicated for, but not limited to, surgical wound infection with coag [sic] negative Staph requiring IV antibiotics and vacuum drainage, subsequent large pulmonary embolism requiring anticoagulation and ruptured gall bladder." (*Id.*) Dr. Shull further explained that Ottinger "required PT and OT in addition to wound vacuum drainage, dressing changes[,] and IV antibiotics via [a peripherally-inserted central catheter] line." (*Id.*)

As of mid-September 2009, Ottinger had improved, and the only remaining care she required was the provision of IV antibiotics and wound care. (AR 152.) Meanwhile,

she was suffering from depression as a result of the emotional and psychological stress associated with enduring multiple prolonged medical admissions and living away from home for an extended period. (AR 151-53, 179-81.) In consideration of these issues, as well as Ottinger's physical condition, Ottinger's physicians, including Dr. Shull and Dr. Kristen Pierce, who treated Ottinger at the Fletcher Allen Health Care Infectious Disease Clinic, decided that the best physical and emotional treatment plan for Ottinger was to send her home and continue her IV antibiotic therapy there. (AR 152-53.) Accordingly, on September 11, 2009, Ottinger was discharged, and daptomycin was administered to her at home via IV for approximately two weeks. (AR 148.) At or around the time of her discharge, Ottinger signed an Advance Beneficiary Notice of Noncoverage (ABN) which stated that "[d]aptomycin administered via pump is *not covered* in the home setting by Medicare A or B." (AR 46 (emphasis added).) The ABN was issued by Apria Healthcare, Inc. (Apria), the company that provided Ottinger with the IV daptomycin and related supplies at her home.

## II. Procedural Background

Apria submitted Medicare claims for Ottinger's IV daptomycin and supplies in the amount of approximately $14,000. (AR 148.) NHIC Corp., a durable medical equipment Medicare Part B contractor for the State of Vermont, denied coverage for these claims. (AR 126.) Ottinger requested reconsideration, and NHIC again denied coverage. (AR 138-39.) Ottinger, through her husband, requested review of NHIC's denial by a qualified independent contractor (QIC), arguing that, "the use of [d]aptomycin and related equipment was medically necessary, and this was determined by a team of well-

qualified doctors." (AR 125.) The QIC upheld NHIC's decision, and denied coverage, explaining: "Medicare does not allow an external infusion pump, infusion supplies, and maintenance of a catheter when the drug used in the infusion therapy is not a covered drug. Daptomycin is not covered because an infusion pump is not needed to dispense the drug." (AR 118.)

Ottinger requested a hearing before an administrative law judge (ALJ), which was held on April 14, 2011. (AR 162-85.) Ottinger was represented at the hearing by Attorney William Dysart, and her husband and daughter testified on her behalf. Ottinger's husband, Harvey Ottinger, testified that Ottinger's discharge and receipt of IV daptomycin at home was a "medical decision" that was made by Drs. Pierce and Scholl and not by Ottinger or her family members. (AR 178.) He explained that Ottinger and her family were "just following the best medical advice given to us." (*Id.*) Ottinger's daughter, Judy Gover, testified that, had she known she could have administered daptomycin to Ottinger by injection, she "would have done it," but she did not know that was an option. (AR 181.)

**III. ALJ/MAC Decision**

In May 2011, the ALJ issued a decision finding that the costs of the infusion pump and supplies provided to Ottinger in September 2009 were not covered under Medicare Part B. (AR 20-26.) The ALJ reasoned that there was no evidence indicating Ottinger's daptomycin was "*required*" to be administered by infusion pump, and thus Ottinger had failed to meet the coverage criteria set forth in the applicable Local Coverage Determination (LCD), LCD L5044. (AR 25.) Ottinger appealed the ALJ's decision to

the Medicare Appeals Council (MAC). (AR 10-13.) In November 2011, the MAC issued a decision concurring with the ALJ's ultimate decision but modifying the analysis contained therein "to clarify the legal basis" for the denial of coverage. (AR 4; *see* AR 3-8.) Specifically, the MAC found that, regardless of whether the administration of daptomycin to Ottinger via IV was medically appropriate or whether the drug was needed to treat Ottinger's condition, Ottinger failed to demonstrate that the drug and associated supplies satisfied the coverage criteria set forth in LCD L5044. (AR 5-6.) The MAC further determined that, given Ottinger's signature on the applicable ABN, Ottinger "knew or could reasonably be expected to know that the items would likely not be covered by Medicare," and thus Ottinger "is liable for the non-covered costs." (AR 8.)

The MAC's decision was the final determination of the Secretary. On January 6, 2012, having exhausted all administrative remedies, Ottinger filed a Complaint against the Secretary, initiating this action. (Doc. 1.)

## Background Law

Title XVIII of the Social Security Act, commonly known as the Medicare Act, 42 U.S.C. § 1395 *et seq.*, establishes the federal government's program of health insurance for the elderly. *Connecticut Dept. of Soc. Servs. v. Leavitt*, 428 F.3d 138, 141 (2d Cir. 2005). Claimants have the burden of proving their entitlement to Medicare benefits. *Keefe v. Shalala*, 71 F.3d 1060, 1062 (2d Cir. 1995); *Friedman v. Sec'y of Dept. of Health and Human Servs.*, 819 F.2d 42, 45 (2d Cir. 1987). The Medicare statute unambiguously vests final authority in the Secretary to determine whether reimbursement for services should be made. *Bodnar v. Sec'y of Health and Human Servs.*, 903 F.2d 122,

125 (2d Cir. 1990) (citing 42 U.S.C. § 1395ff(a); *Heckler v. Ringer*, 466 U.S. 602, 617 (1984)). In evaluating a claim for payment, the Secretary must determine whether the relevant services satisfy the fundamental requirement of 42 U.S.C. § 1395y(a), which requires that the services be "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A); *see Holland v. Sullivan*, 927 F.2d 57, 58-59 (2d Cir. 1991). This statutory standard gives the Secretary "wide discretion" to determine whether the numerous medical services and items covered by Medicare are reasonable and necessary in particular circumstances. *Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98, 105 (D. Mass. 2009) (citing *Goodman v. Sullivan*, 891 F.2d 449, 450 (2d Cir. 1989)); *see Heckler*, 466 U.S. at 617.

Medicare has two parts, Parts A and B. Medicare Part A is automatic and premium-free; it provides reimbursement for inpatient hospital services, post-hospital extended care services, home health services, and hospice care. *See McCreary v. Offner* 172 F.3d 76, 78 (D.C. Cir. 1999) (citing 42 U.S.C. §§ 1395c-i). Medicare Part B, at issue here, is a voluntary supplemental program that covers supplementary medical insurance for services such as doctor visits, diagnostic testing, and certain medical supplies. *See* 42 U.S.C. §§ 1395k(a), 1395x(s). Part B reimburses providers and consumers only for those items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1) (A). As stated above, the Secretary has the authority to determine what items and services are deemed "reasonable and necessary." *Stein v. Sec'y of Health & Human Servs.*, 924 F.2d 431, 433 (2d Cir. 1991) (citing 42 U.S.C. § 1395ff(a)(1)).

Medicare Part B benefits are administered by contractors pursuant to contractual agreements with the Secretary. *See* 42 U.S.C. §§ 1395u, 1395kk-1. Among other functions, these contractors are responsible for determining whether items or services billed to the Medicare program satisfy the Part B coverage requirements and, if so, the amount to be paid for such items or services. *Id.*

**Standard of Review**

Judicial review of an administrative decision regarding claims for benefits under the Social Security Act is authorized by 42 U.S.C. § 405(g). The same statute applies with respect to judicial review of Medicare claims; thus, when applying the statute in Medicare cases, "any reference to the 'Commissioner of Social Security' or the 'Social Security Administration' . . . shall be considered a reference to the 'Secretary' or the 'Department of Health and Human Services,' respectively." 42 U.S.C. § 1395ff(b)(1)(A). Like the Commissioner's denial of a disability claim under the Social Security Act, the Secretary's denial of a Medicare claim must be based on substantial evidence and be in accordance with correct legal principles. *See* 42 U.S.C. § 405(g); *Johnson v. Bowen*, 817 F.2d 983, 985 (2d Cir. 1987). Substantial evidence is "'more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Gartmann v. Sec'y of Dept. of Health and Human Servs.*, 633 F. Supp. 671, 679 (E.D.N.Y. 1986) (quoting *Richardson v. Perales*, 402 U.S. 389, 401 (1971)), *disagreed with on other grounds in Bodnar*, 903 F.2d at 125. In determining whether substantial evidence exists, the reviewing court analyzes the record as a whole, meaning that, "in assessing whether the evidence supporting the Secretary's

position is substantial, [courts] will not look at that evidence in isolation but rather will view it in light of other evidence that detracts from it." *Bodnar*, 903 F.2d at 126 (citing *St. Elizabeth Cmty. Hosp. v. Heckler*, 745 F.2d 587, 592 (9th Cir. 1984)).

"The findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g); *see* 42 U.S.C. § 1385ff(b). Moreover, the court may not substitute its own judgment for that of the Secretary, even if it might justifiably have reached a different result upon a de novo review. *Valente v. Sec'y of Health and Human Servs.*, 733 F.2d 1037, 1041 (2d Cir. 1984). The court is not, however, "bound by the Secretary's conclusions or interpretations of law, or an application of an incorrect legal standard." *Gartmann*, 633 F. Supp. at 679. Therefore, "'[b]efore the insulation of the substantial evidence test comes into play, it must first be determined that the facts of a particular case have been evaluated in light of correct legal standards.'" *Id.* at 680 (quoting *Klofta v. Mathews*, 418 F. Supp. 1139, 1142-44 (E.D. Wis. 1976)); *see Bergeron v. Shalala*, 855 F. Supp. 665, 667 (D. Vt. 1994).

**Analysis**

Ottinger asserts that "imminently qualified doctors" made the determination that daptomycin was "medically necessary" for her treatment, and that the medical decision to discharge her so that she could continue receiving that medication at home via IV was "the best medical decision." (Doc. 6 at 1.) The Secretary argues that, even accepting Ottinger's assertions as true, the MAC correctly denied Medicare coverage, given that Ottinger failed to meet the coverage criteria listed in LCD L5044. (Doc. 7.) The applicable law supports the Secretary's position.

The Medicare Act authorizes individual Medicare contractors to issue LCDs, which are defined as "determination[s] by a fiscal intermediary or a carrier under [the Medicare Act] respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis." 42 U.S.C. § 1395ff(f)(2)(B). Although the ALJ and MAC "are not bound by LCDs," they "will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). In this case, NHIC, a durable medical equipment contractor for the State of Vermont, issued an LCD addressing Medicare coverage for external infusion pumps like the one used by Ottinger in September 2009. LCD L5044 states that an external infusion pump is covered for the administration of four specific drugs in particular situations, including for example, (a) the administration of deferoxamine for the treatment of chronic iron overload, and (b) the administration of morphine for the treatment of intractable pain caused by cancer. (AR 48-49.) *See* U.S. Dep't. of Health and Human Servs., Centers for Medicare & Medicaid Servs. (CMS), Medicare Coverage Database, "LCD for External Infusion Pumps (L5044)," *available at* http://www.cms.gov/medicare-coverage-database (last visited Nov. 2, 2012).[2] Daptomycin is not among the drugs listed in LCD L5044, and more specifically daptomycin for infection is not among the indications listed. (*Id.*)

[2] LCD L5044 was in effect at the time of Ottinger's treatment in September 2009, and is still in effect according to the Department of Health and Human Resources' website. *See* U.S. Dep't. of Health and Human Servs., Centers for Medicare & Medicaid Servs. (CMS), Medicare Coverage Database, "LCD for External Infusion Pumps (L5044)," *available at* http://www.cms.gov/medicare-coverage-database (last visited Nov. 2, 2012). The Secretary represents, however, and Ottinger does not dispute, that this LCD has been "intermittently revised" since September 2009. (Doc. 7 at 5.) The Secretary also represents, and Ottinger does not dispute, that "the portions of LCD L5044 that are relevant to this case . . . have not changed since that time, and are still applicable to coverage determinations involving external infusion pumps." (*Id.*)

LCD L5044 also sets forth two sets of criteria, "Criteria set 1" and "Criteria set 2," for the coverage of "other drugs." (AR 50.) Ottinger fails to demonstrate that use of daptomycin via an infusion pump meets Criteria set 1 or 2. Specifically, two of the indications of Criteria set 1 are that (a) an infusion pump is "necessary to safely administer the drug," and (b) the drug must be "administered by a prolonged infusion of at least 8 hours because of proven improved clinical efficacy." (AR 50.) One of the indications of Criteria set 2 is that "[s]ystemic toxicity or adverse effects of the drug is unavoidable without infusing it at a strictly controlled rate." (*Id.*) Even assuming that daptomycin was needed to treat Ottinger's condition, that the administration of daptomycin by IV was medically appropriate, and that the decision to administer daptomycin by IV in Ottinger's home was reasonable; the MAC properly found that the evidence submitted by Ottinger failed to demonstrate that any of these three listed indications set forth in Criteria set 1 or 2 exist here.

Ottinger's evidence includes letters from two of her treating physicians explaining the benefits of having daptomycin administered to her in her home. Specifically, Dr. Pierce stated as follows:

> In an effort to ensure Ms. Ottinger was receiving *the best therapy to meet both her physical and emotional needs*, the decision was made to send her home to continue her antibiotic therapy. At that time, I felt the *best decision* for her antibiotic therapy was for her to continue with the [d]aptomycin intravenously. I did not feel it was medically appropriate or safe for her to transition to oral antibiotics at the time of her discharge from rehab.

(AR 153 (emphases added).) Dr. Shull similarly stated:

> It was felt by all involved in Mrs. Ottinger's care that, if medically safe, returning her to her home would be *beneficial to her and her family and cost effective*. The only medical reasons to continue her stay at rehab were for IV antibiotics and wound care. With [visiting nurse association] support and family care this could be accomplished in [Ottinger's] home. Therefore, the medical decision was made to discharge [Ottinger] to home and to continue medical treatment there, at *great savings in cost and tremendous benefit* to [Ottinger] and her family.

(AR 152 (italics added).) Although these statements clearly reflect these providers' respective opinions that Ottinger's receipt of daptomycin intravenously at home was the best treatment approach for Ottinger and both beneficial and cost-effective for her and her family, these are not the relevant standards in determining whether Medicare coverage exists in this case. As explained above, LCD L5044 provides for coverage only if, among other things, an infusion pump was necessary to safely administer the daptomycin; the daptomycin had to be administered by a prolonged infusion of at least 8 hours; and systemic toxicity or adverse effects of the daptomycin would have been unavoidable if it had not been infused at a strictly controlled rate. The letters of Ottinger's physicians do not address these factors.

Even if Ottinger's evidence, including the physician letters, could be construed to demonstrate that Criteria set 1 or set 2 of LCD L5044 was met, coverage of "other drugs" is limited under the LCD to eight specific categories of drugs, none of which includes daptomycin. (AR 50-51.) Ottinger's representative at the administrative hearing admitted this fact, stating: "Daptomycin or infections are not indicated as the type of condition that would be covered [under LCD L5044]." (AR 175.) Thus, even if Ottinger

was able to establish that Criteria set 1 or set 2 was met, her use of daptomycin via IV still would not be covered under Medicare.

Ottinger's claim appears to rely on the mistaken assertion that once a physician has concluded that a service or item is medically necessary and beneficial to the patient, the Secretary cannot deny reimbursement under Medicare. In fact, however, "Congress has not provided that all medically necessary items or services must be covered under Medicare Part B." *Goodman v. Sullivan*, 712 F. Supp. 334, 338 (S.D.N.Y. 1989). As another district court in this circuit stated: "While Congress created specific exclusions from coverage and provided that in no case may payment be made for any expenses incurred for items and services which 'are not reasonable and necessary for the diagnosis or treatment of illness or injury,' *it never provided that payment must be made at all times when services are deemed 'medically necessary*.'" *Id.* (emphasis added) (quoting 42 U.S.C. § 1395y(a)(1)(A)). Rather, as explained above, Congress delegated to the Secretary the authority to promulgate regulations for administering the Medicare program, 42 U.S.C. § 1395hh(a), and provided the Secretary with great discretion in determining what items or services will be covered under Medicare Part B. *Goodman*, 712 F. Supp. at 338. Here, LCD L5044 provides that, where the coverage criteria set forth therein is not met, "[e]xternal infusion pumps and related drugs and supplies will be denied as not reasonable and necessary." (AR 53.) Because Ottinger's use of an infusion pump to administer daptomycin does not meet the coverage criteria set forth in LCD L5044, the Court finds that the Secretary properly denied her claim for coverage.

The Court further finds that Ottinger is not relieved from liability under the Medicare statute's "limitation on liability" provision. *See* 42 U.S.C. § 1395pp; 42 C.F.R. § 411.404. That provision provides that, if the individual Medicare beneficiary did not know (and could not reasonably have been expected to know) that a service was not covered, but the provider of services did know (or could have been expected to know) of the non-coverage, then Medicare will deny payment to the provider, but the individual beneficiary will have no liability to the provider or to Medicare. *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 78 n.5 (2d Cir. 2006) (citing 42 U.S.C. § 1395pp(b)). A Medicare beneficiary is considered to have known that services were not covered if written notice has been given to the beneficiary or someone acting on his or her behalf, explaining that "the services were not covered because they did not meet Medicare coverage guidelines." 42 C.F.R. § 411.404(b). This notice may be given by the fiscal intermediary, or "the provider, practitioner, or supplier that furnished the service." 42 C.F.R. § 411.404(c).

Here, it is undisputed that Ottinger signed an ABN from Apria, the provider of the daptomycin, infusion pump, and related supplies, which included the following language: "Daptomycin administered via pump is not covered in the home setting by Medicare A or B. The medication does not meet Medicare criteria for coverage. Therefore the pump pole and supplies are not covered." (AR 46.) This ABN provided adequate notice of non-coverage to Ottinger. *See Almy v. Sebelius*, 749 F. Supp. 2d 315, 335 (D. Md. 2010) ("[A]n ABN may successfully protect the supplier from liability if it specif[ies] the service and a genuine reason that denial by Medicare is expected.") (quotation marks

omitted). Ottinger testified at the administrative hearing that she did not recall signing this ABN (AR 182), but then admitted that she was "very happy about going home [from rehab] . . . [and] would have signed anything" (AR 183).[3] Given these facts, the Court finds that substantial evidence supports the Secretary's conclusion that Ottinger "knew or could reasonably be expected to [have known] that the [infusion pump and related supplies] would likely not be covered by Medicare" (AR 8), and thus Ottinger may not receive shelter from liability for the cost of these items under 42 U.S.C. § 1395pp.

## Conclusion

For these reasons, the Court DENIES Ottinger's motion (Doc. 6), GRANTS the Secretary's motion (Doc. 7), and DISMISSES Ottinger's Complaint in its entirety.

Dated at Burlington, in the District of Vermont, this 28th day of November, 2012.

/s/ John M. Conroy
John M. Conroy
United States Magistrate Judge

[3] Similarly, at the November 2012 hearing before this Court, Ottinger stated that when she signed the ABN, she was unaware of what it said and would have signed anything to facilitate her discharge from the Rehabilitation Center and release home.